Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: Actiq® Lozenges

Prepared for: Missouri Medicaid

Prepared by: Heritage Information Systems, Inc.

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: To promote prudent prescribing and to reduce the costs associated with Actiq® (oral transmucosal fentanyl citrate).

Why was this Issue Selected: For the previous reporting period (August 2001 – July 2002), Missouri Medicaid paid $310,580 for fentanyl lozenges.

Program-specific information:

Drug	Claims	Expense
• Actiq® (oral transmucosal fentanyl citrate)	*428*	*$310,580*

Setting & Population:

Type of Criteria:
☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Non-Preferred Agent**
☒ **Other:** Dose/Quantity

Data Sources:
☐ **Only administrative databases**
☐ **Databases + Prescriber-supplied**

Purpose of PA Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Prior authorization criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Prior authorization criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

Actiq® (oral transmucosal fentanyl citrate), a potent opioid analgesic, received approval from the Food and Drug Administration (FDA) for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.[1,2,3,4] According to the package insert, patients who are considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 mcg transferal fentanyl/hour, or an equianalgesic dose of another opioid for at least a week.[1] Furthermore, Actiq® is contraindicated in the management of acute or postoperative pain because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates and for patients who are not tolerant to opioid therapy.[1,2,3,4]

Actiq® has a unique formulation. It is a dosage form of fentanyl citrate that is intended for oral transmucosal administration in cancer patients. The medicine is in the form of a flavored sugar lozenge that dissolves in the mouth while held by an attached handle. The handle allows the medicine to be removed from the mouth if signs of excessive opioid effects appear during administration. The unit can be consumed in approximately 15 minutes and patients may experience some pain relief while Actiq® is being consumed.[3]

Actiq® is available in six strengths equivalent to 200, 400, 600, 800, 1200, or 1600 mcg fentanyl citrate.[2] Actiq® should only be written by oncologists or pain specialists who are knowledgeable and skilled in the use of a Schedule II opioid to treat cancer pain.[2] The recommended adult dose for Actiq® is initially 200 mcg over 15 minutes and, if needed, the dose may be repeated 15 minutes after the first dose, but no more than two dose units for each pain episode.[3] The maximum daily dose is four dose units. If a patient has more than four episodes of breakthrough pain each day, the dose of the background analgesic needs to be adjusted.[1]

The appropriate pediatric dosing and safety of Actiq® have not been established in children below the age of 16 years.[1] It is essential that healthcare professionals communicate to their patients that Actiq® contains a medicine in a dose that is fatal to a child. The package insert recommends that patients and their caregivers keep all units of Actiq® out of the reach of children.[1] Partially used dose units are a potential risk to children and, therefore, should be discarded properly in a secured container.[1]

In conclusion, Actiq® may be used to treat many types of breakthrough cancer pain. Therefore, it is essential that healthcare professionals evaluate the need for Actiq® on an individual basis and to determine if Actiq® is the most appropriate and cost-effective therapy.

Setting & Population

- Drug class for review: Actiq® (oral transmucosal fentanyl citrate)
- Age range: All ages
  - Claims for patients 18 years of age and under subject to clinical review
- Gender: males and females

Approval Criteria

Approval Diagnoses

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Cancer	140 - 239	NA	2 years	
	NA	Antineoplatics	12 months	
Opioid Tolerance	NA	Opioids	> 7 days supply in the last 30 days	

Denial Criteria

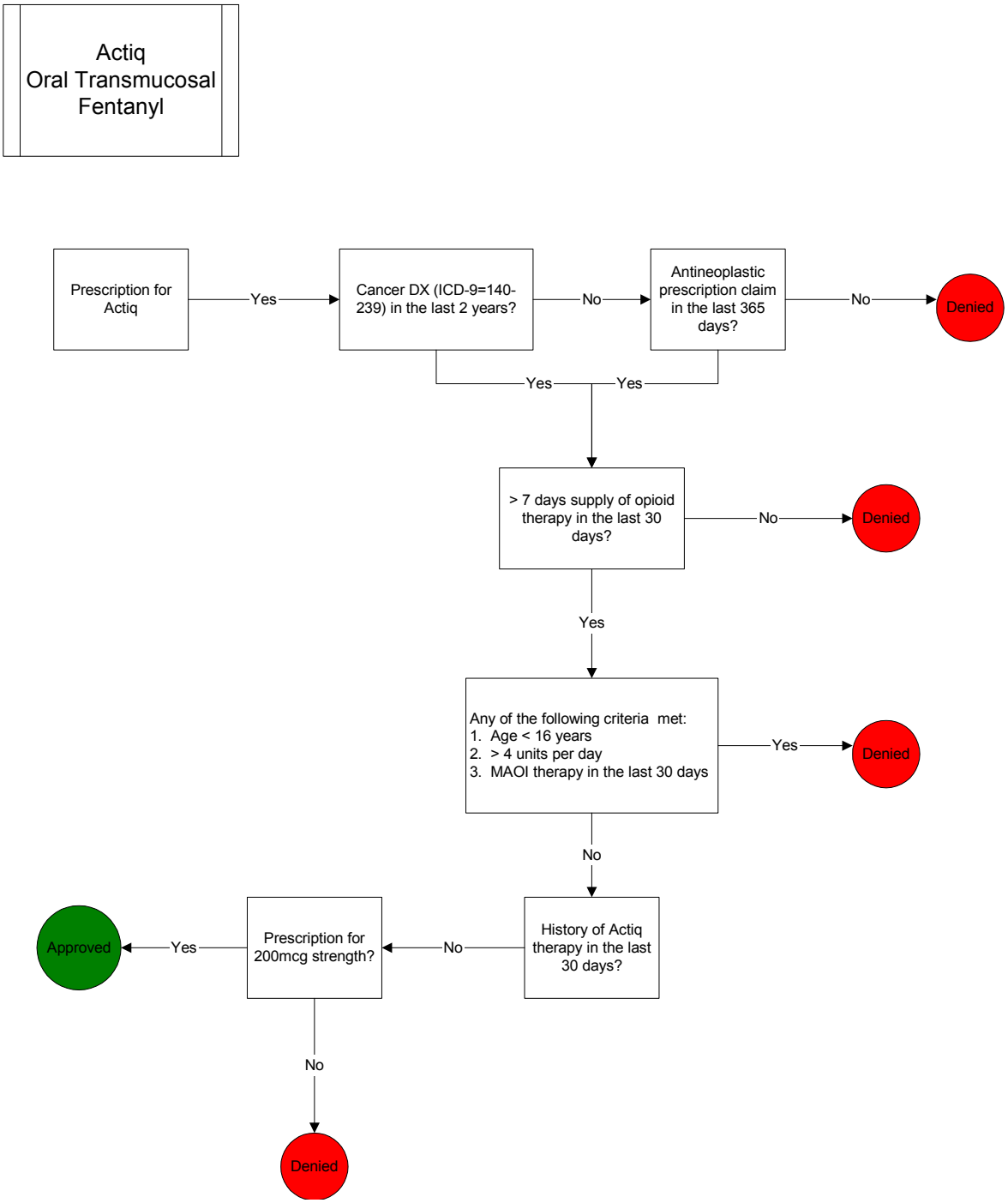
Therapy will be denied if the patients meets any of the following criteria:

- MAOI history in the last 30 days
- Actiq doses > 200mcg used for initial therapy. Initial therapy will be defined as patient not having Actiq therapy in the last 30 days.
- Non cancer diagnois
- > 4 units per day

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐	Other:	☐

Flowchart of Criteria



References

1. Actiq® Package Insert. Westchester, PA: Cephalon; 2002.
2. Drug Facts & Comparison, 2002.
3. British National Formulary, March 2002. http://www.bnf.vhn.net/bnf/documents/bnf.941.html
4. Physicians' Desk Reference, 2002.
5. Hart A and Hopkins C. ICD-9-CM Expert for physicians, volumes 1 and 2. 6th edition. 2002.

Client Approval

Please have an authorized representative execute this PA criteria verifying receipt by the client and that all elements contained herein are understood.

Client Name: _____

Signature: _____

Date: _____